

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

ELIZABETH KINKLE, WENDY KRUSZEWSKI, LINDA KUSZAJ, DEVIK LAW, JERINE LAWLER, DENITTA LAWSON, RANDY LEAKS, CALVIN LEE, WILLIE LEE, JAMES DOUGLAS LOTT JR., RAYMOND LUCERO, MARIO LUNGELOW, ANGELA MATHISON, KATHY J. MCCAULLEY, LINDA D. MCKEE, GERARD MCMILLAN, SHARON G. MEADE, LISA MELFI, JAMES MIDGETTE, TRYPHENA MONDS, KEISHA MONTGOMERY, CARRIE A. MOORE, EARLINE MOORE, ROBIN MOORE, SUSAN MORENO, DANA L. MOSCHELLA, CLAYTON MOUNTS, KEITH MURPHY, BRENDA L. MYERS, DARLENE NEWMAN, JOSHUA P. NEWMAN, ANTHONY NICHOLAS, JOHN NOLES, MICHAEL J. ONORATO, JOHN D. ORCUTT, CARRIE OSTENSON, PAULA OYOLA, MAETAJIA PEOPLES, FRANCES PHILLIPS, MONICA PHIPPS, JOSH PIASECKI, DEBRA D. PINION, MEGAN PINNELL, LISA PINTO, SAM PONCE, DARLENE POWELL, DUSTY PRICE, LINDA PROSKA, DEBBIE PYATOK, JASON REITHER, RICARDO RESTO, JOSHUA ROBERDS, MARILYN ROBINSON, WILMA R. ROBINSON SCOTT, STEPHANIE ROGERS, JOHN ROHRMAN, FRANKIE RUDOLPH, ERIC RUFFIN, JOAN RUNGE, VINCENT SANDERS, ANTHONY SANTEYAN, JENNIFER DAWN SAUNDERS, FABIAN RAY SCOTT, JESUS AYON SEOANE, TAYLOR SHARP, ASHLEY L. SHINN, DAWN E. SIEWERT, ANTHONY SIMON, CAROLYN B. SINCLAIR, AAMINAH NICOLE SMITH, LINDA A. SMITH, MICHAEL SMITH, STEVEN SMITH, VALERIE R. SNYDER, and CLARA SOSA

C.A. No.

Plaintiffs,

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v.

BRISTOL-MYERS SQUIBB COMPANY,  
OTSUKA AMERICA  
PHARMACEUTICAL, INC., and OTSUKA  
PHARMACEUTICAL CO., LTD.,

Defendants.

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**COMPLAINT FOR DAMAGES  
AND DEMAND FOR JURY TRIAL**

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Plaintiffs, ELIZABETH KINKLE, WENDY KRUSZEWSKI, LINDA KUSZAJ, DEVIK  
LAW, JERINE LAWLER, DENITTA LAWSON, RANDY LEAKS, CALVIN LEE, WILLIE  
LEE, JAMES DOUGLAS LOTT JR., RAYMOND LUCERO, MARIO LUNGELOW,  
ANGELA MATHISON, KATHY J. MCCAULLEY, LINDA D. MCKEE, GERARD  
MCMILLAN, SHARON G. MEADE, LISA MELFI, JAMES MIDGETTE, TRYPHENA  
MONDS, KEISHA MONTGOMERY, CARRIE A. MOORE, EARLINE MOORE, ROBIN  
MOORE, SUSAN MORENO, DANA L. MOSCHELLA, CLAYTON MOUNTS, KEITH  
MURPHY, BRENDA L. MYERS, DARLENE NEWMAN, JOSHUA P. NEWMAN,  
ANTHONY NICHOLAS, JOHN NOLES, MICHAEL J. ONORATO, JOHN D. ORCUTT,  
CARRIE OSTENSON, PAULA OYOLA, MAETAJIA PEOPLES, FRANCES PHILLIPS,  
MONICA PHIPPS, JOSH PIASECKI, DEBRA D. PINION, MEGAN PINNELL, LISA PINTO,

SAM PONCE, DARLENE POWELL, DUSTY PRICE, LINDA PROSKA, DEBBIE PYATOK, JASON REITHER, RICARDO RESTO, JOSHUA ROBERDS, MARILYN ROBINSON, WILMA R. ROBINSON SCOTT, STEPHANIE ROGERS, JOHN ROHRMAN, FRANKIE RUDOLPH, ERIC RUFFIN, JOAN RUNGE, VINCENT SANDERS, ANTHONY SANTEYAN, JENNIFER DAWN SAUNDERS, FABIAN RAY SCOTT, JESUS AYON SEOANE, TAYLOR SHARP, ASHLEY L. SHINN, DAWN E. SIEWERT, ANTHONY SIMON, CAROLYN B. SINCLAIR, AAMINAH NICOLE SMITH, LINDA A. SMITH, MICHAEL SMITH, STEVEN SMITH, VALERIE R. SNYDER, and CLARA SOSA, by and through their undersigned counsel, hereby file this Complaint, and make these allegations based on information and belief against Defendants, BRISTOL-MYERS SQUIBB COMPANY, OTSUKA AMERICA PHARMACEUTICAL, INC., and OTSUKA PHARMACEUTICAL CO., LTD. (collectively “Defendants”):

### **INTRODUCTION**

1. This is an action for damages related to Defendants’ wrongful conduct in connection with the development, design, testing, labeling, packaging, promoting, advertising, marketing, distribution, and selling of Defendants’ prescription drug(s) Abilify®, Abilify Maintena®, and Aristada® (hereinafter “Abilify”).

2. Defendants manufacture, promote, and sell Abilify as a prescription drug that treats schizophrenia, depression, bipolar I disorder, irritability associated with autism in adolescents and Tourette’s Disorder. Abilify is manufactured as tablets, oral solution, and injection. Tens of thousands of individuals are prescribed Abilify each year.

3. Abilify injured Plaintiffs by causing harmful compulsive behaviors including compulsive gambling, compulsive shopping and hyper-sexuality. These compulsive behaviors resulted in substantial financial, mental, and physical damages.

4. Defendants knew or should have known that Abilify, when taken as prescribed and intended, causes and contributes to an increased risk of serious and dangerous side effects including, without limitation, uncontrollable compulsive behaviors such as compulsive gambling.

5. Defendants' labeling in the United States, Europe and Canada now warn about the risk of pathological gambling and other compulsive behaviors.

6. Defendants did not warn, advise, educate, or otherwise inform Abilify users or prescribers in the United States about the risk of compulsive gambling or other compulsive behaviors. Prior to January 2016, the U.S. label made no mention of pathological gambling or compulsive behaviors whatsoever. In January 2016, Defendants simply added "pathological gambling" to the postmarketing experience section of the U.S. label. Defendants did not, however, make any mention of gambling or compulsive behaviors in the patient medication guide, the source of information most likely viewed by physicians and patients.

7. On May 3, 2016, the FDA announced that warnings regarding "compulsive or uncontrollable urges to gamble, binge eat, shop, and have sex" would be added to the Abilify label. In August 2016, warnings regarding compulsive gambling and other compulsive behaviors were added to the Abilify label, informing patients and physicians for the first time about these horrific and life-altering side effects. The label now warns that "[b]ecause patients may not recognize these behaviors as abnormal, it is important for prescribers to ask patients or their caregivers specifically about the development of new or intense gambling urges,

compulsive sexual urges, compulsive shopping, binge or compulsive eating, or other urges while being treated with aripiprazole....Compulsive behaviors may result in harm to the patient and others if not recognized. Consider dose reduction or stopping the medication if a patient develops such urges.”

8. Because of Defendants’ actions and inactions, Plaintiffs were injured and suffered damages from their use of Abilify.

### **JURISDICTION AND VENUE**

9. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 (a)(1) in that this action seeks monetary relief in excess of \$75,000.00, exclusive of interest, costs and attorney's fees, and is between citizens of different States.

10. This Court has jurisdiction over Defendants as they are either Delaware corporations or subject to jurisdiction pursuant to and 10 Del. C. § 3104.

11. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(3) because two of the Defendants reside in this judicial district and all are engaged in substantial, systematic and continuous business contacts with this judicial district such that they are all subject to personal jurisdiction here.

### **THE PARTIES**

#### **Plaintiffs**

12. Plaintiff ELIZABETH KINKLE is a resident of Sparks, Nevada, and was prescribed Abilify in Nevada. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. ELIZABETH KINKLE has suffered damages as a result of Defendants’ illegal and wrongful conduct alleged herein.

13. Plaintiff WENDY KRUSZEWSKI is a resident of Lakewood, Ohio, and was prescribed Abilify in Ohio. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. WENDY KRUSZEWSKI has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

14. Plaintiff LINDA KUSZAJ is a resident of East Hartford, Connecticut, and was prescribed Abilify in Connecticut. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. LINDA KUSZAJ has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

15. Plaintiff DEVIK LAW is a resident of Montgomery, Alabama, and was prescribed Abilify in Alabama. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. DEVIK LAW has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

16. Plaintiff JERINE LAWLER is a resident of Kent, Ohio, and was prescribed Abilify in Ohio. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. JERINE LAWLER has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

17. Plaintiff DENITTA LAWSON is a resident of Oklahoma City, Oklahoma, and was prescribed Abilify in Oklahoma. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. DENITTA LAWSON has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

18. Plaintiff RANDY LEAKS is a resident of Thomasville, Georgia, and was prescribed Abilify in Georgia. Abilify was developed, RANDY LEAKS has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

19. Plaintiff CALVIN LEE is a resident of Philadelphia, Pennsylvania, and was prescribed Abilify in Pennsylvania. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. CALVIN LEE has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

20. Plaintiff WILLIE LEE is a resident of Portland, Oregon, and was prescribed Abilify in Oregon. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. WILLIE LEE has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

21. Plaintiff JAMES DOUGLAS LOTT JR. is a resident of Portland, Oregon, and was prescribed Abilify in Oregon. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. JAMES DOUGLAS LOTT JR. has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

22. Plaintiff RAYMOND LUCERO is a resident of Beaverton, Oregon, and was prescribed Abilify in Oregon. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. RAYMOND LUCERO has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

23. Plaintiff MARIO LUNGELOW is a resident of Cincinnati, Ohio, and was prescribed Abilify in Ohio. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. MARIO LUNGELOW has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

24. Plaintiff ANGELA MATHISON is a resident of Twin Falls, Idaho, and was prescribed Abilify in Idaho. Abilify was developed, manufactured, promoted, marketed,

packaged, distributed, and sold by Defendants. ANGELA MATHISON has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

25. Plaintiff KATHY J. MCCAULLEY is a resident of Huntsville, Alabama, and was prescribed Abilify in Alabama. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. KATHY J. MCCAULLEY has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

26. Plaintiff LINDA D. MCKEE is a resident of Sheffield Lake, Ohio, and was prescribed Abilify in Ohio. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. LINDA D. MCKEE has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

27. Plaintiff GERARD MCMILLAN is a resident of Falls Church, Virginia, and was prescribed Abilify in Virginia. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. GERARD MCMILLAN has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

28. Plaintiff SHARON G. MEADE is a resident of New Castle, Indiana, and was prescribed Abilify in Indiana. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. SHARON G. MEADE has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

29. Plaintiff LISA MELFI is a resident of Grove City, Ohio, and was prescribed Abilify in Ohio. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. LISA MELFI has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.



30. Plaintiff JAMES MIDGETTE is a resident of Cleveland, Ohio, and was prescribed Abilify in Ohio. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. JAMES MIDGETTE has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

31. Plaintiff TRYPHENA MONDS is a resident of Decatur, Georgia, and was prescribed Abilify in Georgia. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. TRYPHENA MONDS has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

32. Plaintiff KEISHA MONTGOMERY is a resident of Evansdale, Iowa, and was prescribed Abilify in Iowa. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. KEISHA MONTGOMERY has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

33. Plaintiff CARRIE A. MOORE is a resident of Hobart, Indiana, and was prescribed Abilify in Indiana. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. CARRIE A. MOORE has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

34. Plaintiff EARLINE MOORE is a resident of Kansas City, Kansas, and was prescribed Abilify in Kansas. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. EARLINE MOORE has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

35. Plaintiff ROBIN MOORE is a resident of Napoleon, Ohio, and was prescribed Abilify in Ohio. Abilify was developed, manufactured, promoted, marketed, packaged,

distributed, and sold by Defendants. ROBIN MOORE has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

36. Plaintiff SUSAN MORENO is a resident of Calumet Park, Illinois, and was prescribed Abilify in Illinois. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. SUSAN MORENO has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

37. Plaintiff DANA L. MOSCHELLA is a resident of Shinnston, West Virginia, and was prescribed Abilify in West Virginia. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. DANA L. MOSCHELLA has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

38. Plaintiff CLAYTON MOUNTS is a resident of Middletown, Connecticut, and was prescribed Abilify in Connecticut. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. CLAYTON MOUNTS has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

39. Plaintiff KEITH MURPHY is a resident of Virginia Beach, Virginia, and was prescribed Abilify in Virginia. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. KEITH MURPHY has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

40. Plaintiff BRENDA L. MYERS is a resident of Monroeville, Pennsylvania, and was prescribed Abilify in Pennsylvania. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. BRENDA L. MYERS has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

41. Plaintiff DARLENE NEWMAN is a resident of McSherrystown, Pennsylvania, and was prescribed Abilify in Pennsylvania. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. DARLENE NEWMAN has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

42. Plaintiff JOSHUA P. NEWMAN is a resident of Las Vegas, Nevada, and was prescribed Abilify in Nevada. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. JOSHUA P. NEWMAN has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

43. Plaintiff ANTHONY NICHOLAS is a resident of Hazelton, Pennsylvania, and was prescribed Abilify in Pennsylvania. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. ANTHONY NICHOLAS has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

44. Plaintiff JOHN NOLES is a resident of Cleveland, Ohio, and was prescribed Abilify in Ohio. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. JOHN NOLES has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

45. Plaintiff MICHAEL J. ONORATO is a resident of Chicago, Illinois, and was prescribed Abilify in Illinois. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. MICHAEL J. ONORATO has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

46. Plaintiff JOHN D. ORCUTT is a resident of Skiatook, Oklahoma, and was prescribed Abilify in Oklahoma. Abilify was developed, manufactured, promoted, marketed,

packaged, distributed, and sold by Defendants. JOHN D. ORCUTT has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

47. Plaintiff CARRIE OSTENSEN is a resident of Henderson, Nevada, and was prescribed Abilify in Nevada. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. CARRIE OSTENSEN has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

48. Plaintiff PAULA OYOLA is a resident of Middletown, Connecticut, and was prescribed Abilify in Connecticut. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. PAULA OYOLA has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

49. Plaintiff MAETAJIA PEOPLES is a resident of Chicago, Illinois, and was prescribed Abilify in Illinois. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. MAETAJIA PEOPLES has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

50. Plaintiff FRANCES PHILLIPS is a resident of Shawnee, Oklahoma, and was prescribed Abilify in Oklahoma. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. FRANCES PHILLIPS has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

51. Plaintiff MONICA PHIPPS is a resident of Des Moines, Iowa, and was prescribed Abilify in Iowa. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. MONICA PHIPPS has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

52. Plaintiff JOSH PIASECKI is a resident of Parma, Ohio, and was prescribed Abilify in Ohio. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. JOSH PIASECKI has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

53. Plaintiff DEBRA D. PINION is a resident of Fayette, Alabama, and was prescribed Abilify in Alabama. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. DEBRA D. PINION has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

54. Plaintiff MEGAN PINNELL is a resident of Salem, Oregon, and was prescribed Abilify in Oregon. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. MEGAN PINNELL has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

55. Plaintiff LISA PINTO is a resident of West Warwick, Rhode Island, and was prescribed Abilify in Rhode Island. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. LISA PINTO has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

56. Plaintiff SAM PONCE is a resident of Las Vegas, Nevada, and was prescribed Abilify in Nevada. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. SAM PONCE has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

57. Plaintiff DARLENE POWELL is a resident of Goshen, Indiana, and was prescribed Abilify in Indiana. Abilify was developed, manufactured, promoted, marketed,

packaged, distributed, and sold by Defendants. DARLENE POWELL has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

58. Plaintiff DUSTY PRICE is a resident of Shelbyville, Indiana, and was prescribed Abilify in Indiana. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. DUSTY PRICE has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

59. Plaintiff LINDA PROSKA is a resident of Collingdale, Pennsylvania, and was prescribed Abilify in Pennsylvania. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. LINDA PROSKA has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

60. Plaintiff DEBBIE PYATOK is a resident of Aurora, Colorado, and was prescribed Abilify in Colorado. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. DEBBIE PYATOK has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

61. Plaintiff JASON REITHER is a resident of Mesquite, Nevada, and was prescribed Abilify in Nevada. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. JASON REITHER has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

62. Plaintiff RICARDO RESTO is a resident of Bethlehem, Pennsylvania, and was prescribed Abilify in Pennsylvania. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. RICARDO RESTO has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

63. Plaintiff JOSHUA ROBERDS is a resident of Hillsboro, Ohio, and was prescribed Abilify in Ohio. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. JOSHUA ROBERDS has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

64. Plaintiff MARILYN ROBINSON is a resident of Frisco City, Alabama, and was prescribed Abilify in Alabama. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. MARILYN ROBINSON has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

65. Plaintiff WILMA R. ROBINSON SCOTT is a resident of Dayton, Ohio, and was prescribed Abilify in Ohio. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. WILMA R. ROBINSON SCOTT has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

66. Plaintiff STEPHANIE ROGERS is a resident of Apache Junction, Arizona, and was prescribed Abilify in Arizona. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. STEPHANIE ROGERS has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

67. Plaintiff JOHN ROHRMAN is a resident of Boise, Idaho, and was prescribed Abilify in Idaho. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. JOHN ROHRMAN has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

68. Plaintiff FRANKIE RUDOLPH is a resident of Montgomery, Alabama, and was prescribed Abilify in Alabama. Abilify was developed, manufactured, promoted, marketed,

packaged, distributed, and sold by Defendants. FRANKIE RUDOLPH has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

69. Plaintiff ERIC RUFFIN is a resident of Chicago, Illinois, and was prescribed Abilify in Illinois. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. ERIC RUFFIN has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

70. Plaintiff JOAN RUNGE is a resident of Cullman, Alabama, and was prescribed Abilify in Alabama. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. JOAN RUNGE has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

71. Plaintiff VINCENT SANDERS is a resident of Warner Robins, Georgia, and was prescribed Abilify in Georgia. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. VINCENT SANDERS has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

72. Plaintiff ANTHONY SANTEYAN is a resident of Tucson, Arizona, and was prescribed Abilify in Arizona. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. ANTHONY SANTEYAN has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

73. Plaintiff JENNIFER DAWN SAUNDERS is a resident of Roanoke, Virginia, and was prescribed Abilify in Virginia. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. JENNIFER DAWN SAUNDERS has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.



74. Plaintiff FABIAN RAY SCOTT is a resident of Macon, Georgia, and was prescribed Abilify in Georgia. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. FABIAN RAY SCOTT has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

75. Plaintiff JESUS AYON SEOANE is a resident of Saint Paul, Minnesota, and was prescribed Abilify in Minnesota. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. JESUS AYON SEOANE has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

76. Plaintiff TAYLOR SHARP is a resident of Fairview Heights, Illinois, and was prescribed Abilify in Illinois. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. TAYLOR SHARP has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

77. Plaintiff ASHLEY L. SHINN is a resident of Geary, Oklahoma, and was prescribed Abilify in Oklahoma. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. ASHLEY L. SHINN has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

78. Plaintiff DAWN E. SIEWERT is a resident of Lehighton, Pennsylvania, and was prescribed Abilify in Pennsylvania. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. DAWN E. SIEWERT has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

79. Plaintiff ANTHONY SIMON is a resident of Dayton, Ohio, and was prescribed Abilify in Ohio. Abilify was developed, manufactured, promoted, marketed, packaged,

distributed, and sold by Defendants. ANTHONY SIMON has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

80. Plaintiff CAROLYN B. SINCLAIR is a resident of Montgomery, Alabama, and was prescribed Abilify in Alabama. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. CAROLYN B. SINCLAIR has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

81. Plaintiff AAMINAH NICOLE SMITH is a resident of Cleveland, Ohio, and was prescribed Abilify in Ohio. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. AAMINAH NICOLE SMITH has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

82. Plaintiff LINDA A. SMITH is a resident of Beech Grove, Indiana, and was prescribed Abilify in Indiana. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. LINDA A. SMITH has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

83. Plaintiff MICHAEL SMITH is a resident of Letohatchee, Alabama, and was prescribed Abilify in Alabama. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. MICHAEL SMITH has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

84. Plaintiff STEVEN SMITH is a resident of Philadelphia, Pennsylvania, and was prescribed Abilify in Pennsylvania. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. STEVEN SMITH has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

85. Plaintiff VALERIE R. SNYDER is a resident of Chicago, Illinois, and was prescribed Abilify in Illinois. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. VALERIE R. SNYDER has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

86. Plaintiff CLARA SOSA is a resident of Lawton, Oklahoma, and was prescribed Abilify in Oklahoma. Abilify was developed, manufactured, promoted, marketed, packaged, distributed, and sold by Defendants. CLARA SOSA has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

### **Defendants**

87. When reference is made in this Complaint to any act or omission of any of the Defendants, it shall be deemed that the officers, directors, agents, employees, or representatives of the Defendants committed or authorized such act or omission, or failed to adequately supervise or properly control or direct their employees while engaged in the management, direction, operation, or control of the affairs of Defendants, and did so while acting within the scope of their duties, employment or agency.

88. The term "Defendant" or "Defendants" refers to all Defendants named herein jointly and severally.

89. Upon information and belief, each of the Defendants are responsible, negligently, intentionally, and/or in some actionable manner, for the events and happenings referred to herein, and caused and continue to cause injuries and damages legally thereby to Plaintiffs, as alleged, either through each Defendant's own conduct or through the conduct of their agents, servants, or employees, or due to the ownership, maintenance, or control of the instrumentality causing them injury, or in some other actionable manner.

90. Defendant Bristol-Myers Squibb Company (“Bristol-Myers”) is a corporation organized and existing under the laws of Delaware, with its principal executive office at 345 Park Avenue, New York, New York. Bristol-Myers is in the business of researching, developing, manufacturing, and selling pharmaceuticals. Bristol-Myers does business throughout the United States, including in the state of Delaware.

91. Defendant Otsuka Pharmaceutical Co., Ltd. (“OPC”) is a Japanese company, with its principal office at 2-9, Kanda Tsukasa-machi, Chiyoda-ku, Tokyo 101-8535, Japan, and has a registered agent located at 351 West Camden Street, Baltimore, Maryland based upon information filed with the Maryland Department of Assessments and Taxation Business Services. Abilify is a trademark of Defendant Otsuka Pharmaceutical Co., Ltd. Defendant Otsuka Pharmaceutical Co. Ltd. wholly owns Defendant Otsuka America, Inc. (“OAI”), a holding company established in the United States in or around 1989. OAI is the parent of Defendant Otsuka America Pharmaceutical, Inc. (“OAPI”), Otsuka Pharmaceutical Development & Commercialization, Inc. (“OPDC”), and Otsuka Maryland Medicinal Laboratories, Inc. (“OMML”). OPC and its subsidiaries/alter-egos are in the business of researching, developing, manufacturing, and selling pharmaceuticals.

92. Defendant OAPI is incorporated in Delaware, with its principal place of business at 508 Carnegie Center, Princeton, New Jersey. OAPI developed, distributed, and marketed Abilify with OPC. OAPI does business throughout the United States, including in the state of Delaware.

93. At all times relevant to this Complaint, Defendants OPC, OAI, OAPI, OPDC, and OMML (the “Otsuka entities”) have operated in concert regarding the development, research, distribution, manufacturing, and/or marketing of Abilify. OPC has control over its subsidiaries’

daily affairs and operations with respect to Abilify. The Otsuka entities work in concert as a single operation known as the Otsuka Group. At all times relevant herein, OAPI was the alter-ego of OPC.

94. Defendant Bristol-Myers has operated in concert with the other Defendants and jointly marketed, sold, and promoted Abilify in the United States with the Otsuka Group, through Defendant OAPI and otherwise.

95. Defendants are collectively engaged in the development, design, testing, labeling, packaging, promoting, advertising, marketing, distribution, and selling of pharmaceutical products, including Abilify. OPC “discovered” Abilify in 1988, obtained approval in the United States in November 2002, and in Japan in January 2006.

96. Defendants are and have been engaged in the business of researching, testing, developing, manufacturing, packaging, distributing, licensing, labeling, promoting, marketing and selling, either directly or indirectly through third parties or related entities, the pharmaceutical drug Abilify, in all states and throughout the United States, including Delaware.

97. Defendants conducted, funded, supported, supervised, and contributed to numerous studies and clinical trials about the efficacy, safety, tolerability, and side effect profile of Abilify in Delaware. Hospitals and other healthcare facilities throughout the state of Delaware were chosen and did act as sites for these studies and trials. Upon information and belief, this includes, for example, the studies that formed the basis of the FDA’s decision to indicate Abilify for adjunctive therapy in major depression.

98. Defendants placed Abilify into the stream of commerce with the intent it would be marketed, advertised, and sold in all states and throughout the United States, including in Delaware. Plaintiffs’ use of, and ultimately injury by, Abilify in Delaware and the various other

States of the United States was not an isolated occurrence, but arose from the purposeful efforts of Defendants to create and serve the market for Abilify in Delaware and various other States of the United States by the marketing, advertising, soliciting purchases, and selling of Abilify in those states.

### **FACTUAL ALLEGATIONS AS TO ALL COUNTS**

99. Abilify was first introduced in the United States in or around the fall of 2002. Abilify is an atypical anti-psychotic prescription medicine discovered by Defendant Otsuka Pharmaceutical Co., Ltd.

100. In or around October or November 2012, the European Medicines Agency required Defendants to warn patients and the European medical community that Abilify use included the risk of pathological gambling.

101. In particular, the European Medicines Agency required the European labeling to carry the following language in the “Special Warnings and Precautions For Use” section of the label:

#### **Pathological Gambling**

**Post-marketing reports of pathological gambling have been reported among patients prescribed ABILIFY, regardless of whether these patients had a prior history of gambling. Patients with a prior history of pathological gambling may be at increased risk and should be monitored carefully.**

102. The European labeling for Abilify also carries additional language concerning adverse reactions that have been reported during post-marketing surveillance relating to gambling side effects. Under a section entitled “Undesirable effects,” it provides:

**Psychiatric Disorders: agitation, nervousness, pathological gambling, suicide attempt, suicidal ideation, and completed suicide.**

103. In or around November 2015, Canadian regulators concluded that there is “a link between the use of aripiprazole and a possible risk of pathological gambling or hypersexuality” and found an increased risk of pathological (uncontrollable) gambling and hypersexuality with Abilify use.

104. In or about November 2015, the following warning statement regarding the risk of pathological gambling was added to the Canadian prescribing information for Abilify:

**Pathological Gambling**

**Post-marketing reports of pathological gambling have been reported in patients treated with ABILIFY. In relation to pathological gambling, patients with a prior history of gambling disorder may be at increased risk and should be monitored carefully.**

105. Despite these warnings and advisories in Europe and Canada—for the same drug sold to patients in the United States—the labeling for Abilify in the United States did not adequately warn about the risk of compulsive gambling or other compulsive behaviors and contained no mention that pathological gambling and other compulsive behaviors had been reported in patients prescribed Abilify. It was not until January 2016, after the patent for Abilify expired in the United States, that pathological gambling was added only to the Postmarketing Experience section of the label; Defendants failed to make mention of gambling in the patient medication guide, a source of information likely viewed by physicians and patients. On May 3, 2016, the FDA issued a warning that Abilify was associated with “compulsive or uncontrollable urges to gamble, binge eat, shop, and have sex.” The FDA recommended that doctors “make patients and caregivers aware of the risk of these uncontrollable urges,” “closely monitor” patients, and consider reducing or stopping Abilify if compulsivity emerges.

106. The labeling for Abilify in the United States contained no mention of the word “gambling” until January 2016. It contained no warning about pathological gambling until August 2016.

107. Defendants wrongfully and unjustly profited at the expense of patient safety and full disclosure to the medical community by failing to include language about gambling in the United States labeling and by failing to otherwise warn the public and the medical community about Abilify’s association with gambling—despite opportunities and a duty to do so. As a result, Defendants have made significantly more revenue from Abilify sales in the United States compared to Europe.

108. Bristol-Myers touts Abilify as its “2013 largest-selling product” noting sales of \$2.3 billion. Bristol-Myers recently reported U.S. revenues from Abilify sales of \$417 million over three months ending June 30, 2014, and worldwide revenues of \$555 million over the same time period.

109. Since its introduction to the United States market, Abilify has generally been used to treat patients with schizophrenia, bipolar disorder, as an adjunct for depression, and autism spectrum disorders.

110. In 2001, Defendant Otsuka Pharmaceutical Co., Ltd. submitted a New Drug Application (“NDA”) to the United States Food and Drug Administration (“FDA”) for Abilify (aripiprazole). This initial NDA sought approval to market Abilify in 2, 5, 10, 15, 20 and 30 mg tablets as a treatment for schizophrenia. The NDA was approved on November 15, 2002.

111. In November 2002, the FDA required Defendants to submit results of Study 138047 to address the longer-term efficacy of Abilify in the treatment of adults with schizophrenia.



112. On December 3, 2002, Defendant Otsuka America Pharmaceutical, Inc. submitted a Supplemental New Drug Application (NDA 21-436/S-001) on the longer-term efficacy of Abilify in the treatment of schizophrenia. This application was approved on August 28, 2003.

113. In June 2003, Otsuka Maryland Research Institute submitted another Supplemental New Drug Application (NDA 21-436/S-002) for Abilify tablets as a treatment for bipolar disorder. This application was approved on September 29, 2004.

114. In May 2007, Otsuka Pharmaceutical Development & Commercialization, Inc. submitted another Supplemental New Drug Application (NDA 21-436/S-018) for Abilify tablets as an adjunctive treatment for patients with major depressive disorder. This application was approved on November 16, 2007.

115. In contrast, in Europe, Abilify is not indicated to treat depression. The European Medicines Agency declined to approve Abilify as an add-on treatment for depression because of concerns about its efficacy for that indication.

116. In or around 1999, Bristol-Myers and Otsuka entered into an agreement to co-develop and “commercialize” Abilify (hereinafter referred to as “Defendants’ Marketing Agreement”). Under the terms of Defendants’ Marketing Agreement, Bristol-Myers was to market and promote Abilify in the United States and the European Union, in collaboration with Otsuka Pharmaceutical Co., Ltd., and under Otsuka Pharmaceutical Co., Ltd.’s trademark.

117. Defendants’ Marketing Agreement also provided that Bristol-Myers and Otsuka Pharmaceutical Co., Ltd. would collaborate to complete clinical studies for schizophrenia, and that Bristol-Myers would conduct additional studies for new dosage forms and new indications.

118. Bristol-Myers began co-promoting Abilify with Otsuka Pharmaceutical Co., Ltd. in the United States and Puerto Rico in or around November 2002. Defendants' Marketing Agreement was extended in or around 2009.

119. Bristol-Myers' Marketing Agreement with Otsuka had been due to expire in or around April 2015, just after the predicted expiration of Abilify's patent protection in the United States. According to a revised marketing agreement, Bristol-Myers purported to no longer market and promote Abilify as of January 1, 2013, but agreed to continue to carry out its other responsibilities, including manufacturing for sale to third-party customers. Nevertheless, Bristol-Myers continued to market and promote Abilify, for example, through its website, through September 2015.

120. Defendants knew or should have known that Abilify can cause compulsive behaviors like gambling. Despite their significant collective resources, and signals that Abilify is associated with compulsive behaviors such as gambling and other compulsive behaviors, Defendants failed to fully and adequately test, research or investigate Abilify and its association with compulsive behaviors to the detriment of Plaintiffs, Abilify users, the public, the medical community, and prescribing doctors.

121. Medical providers and patients were unaware of the association between compulsive behaviors like gambling and Abilify. They could not have reasonably known or learned through reasonable diligence of the association.

122. Compulsive gambling is a major psychiatric disorder. The American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders* ("DSM") first recognized pathological gambling as a psychiatric disorder in 1980.

123. Originally, the disorder was classified as an impulse control disorder. The current version of the DSM, the DSM-V, renamed pathological gambling as “gambling disorder.” DSM-V reclassified gambling disorder under the category Substance-Related and Addictive Disorders in order to reflect evidence that gambling behaviors activate or are activated by reward systems similar to those activated by drugs of abuse, and produce some behavioral symptoms comparable to those produced by substance abuse disorders.

124. Abilify is variably a partial and full dopamine agonist. Dopamine is a neurotransmitter that helps control the brain’s reward and pleasure centers.

125. Dopamine’s role in compulsive behavior and pathological gambling is well-known. Dopaminergic reward pathways have frequently been implicated in the etiology of addictive behavior. Scientific literature has identified dopamine as a potential cause of pathological gambling for years.

126. Abilify’s dopaminergic activity at the mesolimbic circuit, especially at the nucleus accumbens, has been associated with compulsive behavior in Abilify patients.

127. Defendants acknowledged that Abilify was a plausible mechanism for pathological gambling in their September 2011 6-Month Periodic Safety Update Report. The Report states that an article, Chau et al., *The Neural Circuitry of Reward and Its Relevance to Psychiatric Disorders*, “does suggest a possible mechanism by which drugs that act on dopamine neurons, like aripiprazole, might possibly have some effect on behavior related to reward.”

128. Defendants’ September 2011 6-Month Periodic Safety Update Report submitted to the European Medicines Agency acknowledged seven serious reports of pathological gambling,

three in the medical literature and four spontaneous reports. The report also noted sixteen cases of pathological gambling in the Bristol-Myers company safety database.

129. The Medical Assessment of the pathological gambling cases in Defendants' September 2011 6-Month Periodic Safety Update Report did not exclude Abilify as the cause of the compulsive gambling adverse events. Defendants concluded that "a causal role of aripiprazole could not be excluded" and that "aripiprazole was suggested by the temporal relationship."

130. The European Final Assessment Report of the September 2011 6-Month Periodic Safety Update Report concluded that with regard to compulsive gambling "in all of the reported cases we have a (+) temporal; (+) dechallenge and in one case a (+) rechallenge."

131. Numerous case reports have been published in the medical literature linking Abilify to compulsive behavior, including at least seventeen cases of compulsive gambling. Gaboriau et al. examined case reports of compulsive gambling and found that the probability that pathological gambling was actually due to Abilify was "possible" in sixteen of the cases and "doubtful" in only one of the cases.

132. Several case reports demonstrate what is known as a challenge, de-challenge, and re-challenge.

133. Challenge is the administration of a suspect product by any route.

134. De-challenge is the withdrawal of the suspected product from the patient's therapeutic regime. A positive de-challenge is the partial or complete disappearance of an adverse experience after withdrawal of the suspect product. For example, a positive de-challenge occurs when a patient ceases use of Abilify and pathological gambling behaviors cease concurrently.

135. Re-challenge is defined as a reintroduction of a product suspected of having caused an adverse experience following a positive de-challenge. A positive re-challenge occurs when similar signs and symptoms reoccur upon reintroduction of the suspect product. For example, a positive re-challenge occurs when a patient reintroduces Abilify into her treatment regime and pathological gambling behavior reoccurs in a similar manner as such behaviors had existed when the patient previously used Abilify.

136. A positive de-challenge is considered evidence that a drug caused a particular effect, as is a positive re-challenge.

137. From May 1, 2008 to May 1, 2011, the FDA received thousands of serious adverse event reports concerning Abilify (n=4599), including over two-thousand serious adverse drug experiences of which 193 involved children (0-16 years old).

138. Serious adverse events are drug experiences including the outcomes of death, life-threatening events, hospitalization, disability, congenital abnormality, and other harmful medical events.

139. From 2005 to 2013, an FDA report showed that Abilify accounted for at least fifty-four reports of compulsive or impulsive behavior problems, including thirty reports of compulsive gambling, twelve reports of impulsive behavior, nine reports of hypersexuality, and three reports of compulsive shopping.

140. A disproportionality study of the FDA Adverse Event Reporting System showed a proportional reporting ratio for compulsivity of 8.6 for Abilify. A ratio of more than three indicates a signal of an adverse event.

141. An analysis of the FDA Adverse Event Reporting System shows an escalating number of reports. Twenty-nine reports of gambling behavior were made to the FDA in 2014.

142. The 2014 FDA Adverse Event Reporting System data shows a proportional reporting ratio for compulsive gambling of 64.3 for Abilify. The same data demonstrates Abilify is unique in this regard and compulsive gambling is not a class-wide problem among anti-psychotic medications.

143. Defendants have not adequately studied Abilify. A review of all the randomized clinical trials comparing Abilify to other schizophrenia drugs concluded that the information on comparisons was of limited quality, incomplete, and problematic to apply clinically.

144. Despite evidence that Abilify causes compulsive behaviors like pathological gambling and calls from the medical community to conduct further research and warn patients about this possible effect of Abilify, Defendants have either failed to investigate or conduct any studies on the compulsive behavior side effects of Abilify or failed to make public the results of any studies or investigations that they might have done.

145. Abilify is not very efficacious. According to a rigorous study by the Cochrane Collaboration, there is limited evidence that Abilify leads to symptom reduction when added to antidepressants, and side effects are more frequent under Abilify augmentation treatment.

146. The Drug Facts Box for Abilify for major depression includes a “summary” of the combined data from the two identical six-week randomized trials that were the basis for FDA drug approval for this indication. The box shows that Abilify has only a modest benefit: on average, patients on Abilify improved by 3 points more (*on a scale of 60*) than patients on placebo, and only an additional 11% of patients had a clinically important response as defined in the trial.

147. Despite the risks of serious adverse events, and the lack of adequate testing, Defendants aggressively promoted Abilify, including illegal promotion for off-label use. In 2007,

Bristol-Myers reportedly paid \$515 million to settle federal and state investigations into off-label marketing of Abilify for pediatric use and to treat dementia-related psychosis. Otsuka America Pharmaceutical, Inc. later paid more than \$4 million to resolve the allegations.

148. The FDA issued a letter dated April 17, 2015 finding Abilify promotional material “false or misleading because it makes misleading claims and presentations about the drug.” The FDA found the material “misleading because it implies that Abilify offers advantages over other currently approved treatments for bipolar disorder or MDD when this has not been demonstrated.” The FDA also found the cited references “not sufficient to support claims and presentations suggesting that Abilify has been demonstrated to modulate dopaminergic and serotonergic activity, or modulate neuronal activity in both hypoactive and hyperactive environments in humans.

149. Upon information and belief, Defendants have invested millions of dollars in teams of pharmaceutical sales representatives who visit and contact members of the medical community, including prescribing doctors, purporting to “educate” them about Abilify. Upon information and belief, these pharmaceutical sales representatives have not notified patients, the medical community, or prescribers in the United States that Abilify causes, is linked to, or might be associated with compulsive gambling, pathological gambling, or gambling addiction.

150. Defendants have also been accused of instructing representatives speaking about Abilify on their behalf pursuant to consultant contracts to deliberately lie to and/or mislead their audiences. For example, celebrity author, bipolar patient, and former Abilify patient spokesperson Andy Behrman alleged in an interview published by the Wall Street Journal that Defendant Bristol-Myers’ employees instructed him to tell audiences that he was on Abilify monotherapy and had not experienced any side effects, despite both of these claims being false.

Upon information and belief, Defendants pursued these types of practices with other paid spokespeople as well, in an effort to overstate the efficacy and downplay the major safety issues of Abilify.

151. Defendants have invested millions of dollars in “Direct to Consumer” advertising. None of the advertising in the United States notifies patients, the medical community, or prescribers that Abilify use causes, is linked to, or might be associated with compulsive gambling, pathological gambling, or gambling addiction.

152. Defendants’ Direct to Consumer advertising minimizes risks while over-promoting the drug.

153. As a result of Defendants’ misleading promotional campaigns, Abilify has occupied the top sales position for a prescription drug in the United States (but has only ever reached seventh place in the global ranking of drug sales).

154. Defendants have made payments to doctors to promote Abilify. From August 2013 to December 2014, \$10.6 million in payments relating to Abilify were made to 21,155 physicians in the United States.

155. To date, Defendants have not adequately notified or warned patients, the medical community, or prescribers in the United States that Abilify causes, is linked to, and is associated with compulsive gambling, pathological gambling, or gambling addiction.

156. Prior to May 2016, upon information and belief, Defendants had not sent out any “Dear Doctor” letters to inform the medical community of the risk or association of Abilify use and gambling.

157. The labeling for Abilify in the United States lists serious side effects that have been reported with Abilify, but did not list gambling, pathological or otherwise in any form until



January 2016 when it was only added to the post-marketing experience section of the label. Prior to May 2016, the label did not mention compulsive behaviors other than pathological gambling or adequately warn patients about the risk of compulsive gambling. Defendants also did not make any mention of gambling in the patient medication guide, the source of information most likely viewed by physicians and patients.

158. The labeling in the United States contradicts the labeling in Europe and Canada by not providing adequate warnings and not cautioning that patients should be closely monitored, and does not adequately inform patients and physicians that gambling and other compulsive behaviors have been associated with Abilify use.

159. Defendant Otsuka America Pharmaceutical, Inc. maintains a website promoting Abilify, [www.abilify.com](http://www.abilify.com). The website includes, among other information, “tips for taking Abilify,” links to “a 30-day free trial & savings on refills,” and “important safety information” for Abilify. Although it has sections about “important safety information,” nowhere on the website did it mention the word “gambling” prior to 2015.

160. Also, Defendant Otsuka America Pharmaceutical, Inc. operated another website promoting Abilify, [www.addabilify.com](http://www.addabilify.com). Prior to 2015, this website included, among other information, “important safety information,” “tips for family and friends,” “treatment FAQs,” “side effects FAQs,” and “what your doctor needs to know” concerning Abilify. Nowhere on the website did it mention the word “gambling.”

161. Defendant Bristol-Myers previously promoted Abilify on its own website, [www.bms.com](http://www.bms.com) (“BMS website”), noting it was approved in November 2002 and is “jointly marketed in the U.S. by Bristol-Myers Squibb and Otsuka America Pharmaceutical.” The BMS

website also included a link to the [www.abilify.com](http://www.abilify.com) website. Nowhere on the BMS website did it mention the word “gambling.”

162. Likewise, Defendant Otsuka Pharmaceutical Co., Ltd. promotes Abilify on its own website, [www.otsuka.co.jp/en/](http://www.otsuka.co.jp/en/) (“Otsuka website”), noting it was “researched and developed by Otsuka Pharmaceutical” and “launched” in the United States in 2002. Nowhere on the Otsuka website does it mention the word “gambling.”

### **EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS**

163. Plaintiffs assert all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including the discovery rule and/or fraudulent concealment.

164. The discovery rule should be applied to toll the running of the statute of limitations until the Plaintiffs discovered or reasonably should have discovered Plaintiffs’ injuries and the causal connection between the injuries and Defendants’ product.

165. Defendants are estopped from asserting a statute of limitations defense because all Defendants fraudulently concealed from Plaintiffs the truth, quality and nature of Plaintiffs’ injuries and the connection between the injuries and Defendants’ tortious conduct. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiffs and Plaintiffs’ prescribing physicians the true risks associated with Abilify.

166. Defendants were under a duty to disclose the true character, quality and nature of the risks associated with use of Abilify as this was non-public information over which Defendants had and continue to have exclusive control. Defendants knew that this information was not available to Plaintiffs, Plaintiffs’ medical providers and/or health-care facilities. In

addition, Defendants are estopped from relying on any statute of limitation because of their intentional concealment of these facts.

167. Plaintiffs had no knowledge that Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by Defendants, Plaintiffs could not have reasonably discovered the wrongdoing at any time prior to 2016.

**AS AND FOR A FIRST CAUSE OF ACTION: STRICT LIABILITY – DESIGN,  
MANUFACTURING AND WARNING**

168. Plaintiffs hereby repeat, reallege, and reiterate each and every allegation in the preceding paragraphs as if fully restated herein.

169. Defendants had a duty to provide adequate warnings and instructions for Abilify, to use reasonable care to design a product that is not unreasonably dangerous to users, and to adequately test their product.

170. The Abilify supplied to Plaintiffs by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer or supplier, it was in an unreasonably dangerous and a defective condition for its intended use and it posed a risk of serious compulsive behaviors and harm to Plaintiffs and other consumers which could have been reduced or avoided, inter alia, by the adoption of a feasible reasonable alternative design.

171. The Abilify supplied to Plaintiffs by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer or supplier, Abilify had not been adequately tested, was in an unreasonably dangerous and a defective condition, and it posed a risk of serious compulsive behaviors and harm to Plaintiffs and other consumers.

172. Also, Abilify's limited and unproven effectiveness did not outweigh the risks posed by the drug. In light of the utility of the drug and the risk involved in its use, the design of Abilify makes the product unreasonably dangerous.

173. The Abilify supplied to Plaintiffs by Defendants was defective due to inadequate warnings or instructions concerning the true risks of its use.

174. Defendants, and each of them, knew and intended that Abilify would be used by the ordinary purchaser or user without inspection for defects therein and without knowledge of the hazards involved in such use.

175. Defendants knew or should have known through testing, scientific knowledge, advances in the field or otherwise, that the product created a risk of serious compulsive behaviors and harm, and was unreasonably dangerous to Plaintiffs and other consumers, about which Defendants failed to warn.

176. The Abilify supplied to Plaintiffs by Defendants was defective, dangerous, and had inadequate warnings or instructions at the time it was sold, and Defendants also acquired additional knowledge and information confirming the defective and dangerous nature of Abilify. Despite this knowledge and information, Defendants failed and neglected to issue adequate warnings or post-sale warnings that Abilify causes serious compulsive behaviors and harm.

177. Defendants failed to provide adequate warnings to users, purchasers, or prescribers of Abilify, including Plaintiffs and prescribing physicians, and instead continued to sell Abilify in an unreasonably dangerous form without adequate warnings or instructions. Defendants knew or should have known that members of the general public and the medical community had no knowledge that Plaintiffs and other users of their product could experience the injuries herein alleged. Defendants also knew or should have known that Plaintiffs and other

users of their product would assume that said use was safe, and that no side effects were likely to exist beyond those of which Defendants had warned.

178. By failing to adequately test and research compulsive behaviors and harms associated with Abilify use, and by failing to provide appropriate warnings about Abilify use and associations with compulsive behaviors such as gambling, patients and the medical community, including prescribing doctors, were inadequately informed about the true risk-benefit profile of Abilify and were not sufficiently aware that compulsive behaviors such as gambling might be associated with Abilify use. As such, the medical community was not learned on the true risk-benefit profile of Abilify. Nor were the medical community, patients, patients' families, or regulators appropriately informed that compulsive behaviors such as gambling might be a side effect of Abilify use and should or could be reported as an adverse event.

179. As a direct and proximate result of Defendants' conduct, including the inadequate warnings, dilution or lack of information, lack of adequate testing and research, and the defective and dangerous nature of Abilify, Plaintiffs suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiffs will suffer the losses in the future.

**AS AND FOR A SECOND CAUSE OF ACTION: BREACH OF EXPRESS WARRANTY**

180. Plaintiffs hereby repeat, reallege, and reiterate each and every allegation in the preceding paragraphs as if fully restated herein.

181. Defendants, who designed, tested, manufactured, packaged, supplied, distributed, marketed, advertised, promoted, recommended, and sold Abilify, expressly warranted to

physicians and consumers, including Plaintiffs and Plaintiffs' physicians, that Abilify was safe and well-tolerated.

182. At the time of making the aforementioned express warranties, Defendants had knowledge of the purpose for which Abilify was to be used, and warranted the same to be in all respects fit, safe, effective, and proper for such purpose. Abilify was unaccompanied by warnings of its dangerous propensities that were either known or should have been known to Defendants at the time of distribution.

183. Abilify does not conform to these express representations because it is neither safe nor well-tolerated. Instead, it significantly increases the risk of the patient engaging in compulsive behaviors such as pathological gambling addiction, which causes monetary losses and in turn can lead to financial ruin, job loss, familial devastation, and suicide attempts.

184. Plaintiffs and their prescribing physicians reasonably relied upon the skill and judgment of Defendants, and upon the aforementioned express warranties, in using and prescribing Abilify. The warranty and representations were untrue in that the product was unsafe, and thus unsuited for the use for which it was intended.

185. As a direct and proximate result of the breach of Defendants' warranties, Plaintiffs suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiffs will suffer the losses in the future.

**AS AND FOR A THIRD CAUSE OF ACTION: BREACH OF IMPLIED WARRANTY**

186. Plaintiffs hereby repeat, reallege, and reiterate each and every allegation in the preceding paragraphs as if fully restated herein.

187. At the time Defendants manufactured, packaged, marketed, sold, and distributed Abilify, Defendants knew of the use for which Abilify was intended, and they impliedly warranted Abilify to be of merchantable quality, safe and fit for such use.

188. Defendants knew, or had reason to know, that Plaintiffs and Plaintiffs' physicians would rely on the Defendants' judgment and skill in providing Abilify for its intended use.

189. Plaintiffs and Plaintiffs' physicians reasonably relied upon the skill and judgment of Defendants as to whether Abilify was of merchantable quality, safe, and fit for its intended use.

190. Contrary to such implied warranty, Abilify was not of merchantable quality or safe or fit for its intended use, because the product was, and is, unreasonably dangerous, defective and unfit for the ordinary purposes for which Abilify was used.

191. Also, Abilify's limited and unproven effectiveness did not outweigh the risks posed by the drug. In light of the utility of the drug and the risk involved in its use, the design of Abilify makes the product unreasonably dangerous.

192. As a direct and proximate result of the breach of implied warranty, Plaintiffs suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiffs will suffer the losses in the future.

**AS AND FOR A FOURTH CAUSE OF ACTION: NEGLIGENCE**

193. Plaintiffs hereby repeat, reallege, and reiterate each and every allegation in the preceding paragraphs as if fully restated herein.

194. At all times material herein, Defendants had a duty to exercise reasonable care and had the duty of an expert in all aspects of the design, formulation, manufacture, compounding, testing, inspection, packaging, labeling, distribution, marketing, promotion, advertising, sale, warning, post-sale warning, testing, and research to assure the safety of the product when used as intended or in a way that Defendants could reasonably have anticipated, and to assure that the consuming public, including Plaintiffs and Plaintiffs' physicians, obtained accurate information and adequate instructions for the safe use or non-use of Abilify.

195. Defendants had a duty to warn Plaintiffs, Plaintiffs' physicians, and the public in general of Abilify's dangers and serious side effects, including serious compulsive behaviors like pathological gambling addiction, since it was reasonably foreseeable that an injury could occur because of Abilify's use.

196. At all times material herein, Defendants failed to exercise reasonable care and the duty of an expert and knew, or in the exercise of reasonable care should have known, that Abilify was not properly manufactured, designed, compounded, tested, inspected, packaged, labeled, warned about, distributed, marketed, advertised, formulated, promoted, examined, maintained, sold, prepared, or a combination of these acts.

197. Each of the following acts and omissions herein alleged was negligently and carelessly performed by Defendants, resulting in a breach of the duties set forth above. These acts and omissions include, but are not restricted to:

- a. Negligent and careless research and testing of Abilify;
- b. Negligent and careless design or formulation of Abilify;



- c. Negligent and careless failure to give adequate warnings that would attract the attention of Plaintiffs, Plaintiffs' physicians, and the public in general of the potentially dangerous, defective, unsafe, and deleterious propensity of Abilify and of the risks associated with its use;
- d. Negligent and careless failure to provide instructions on ways to safely use Abilify to avoid injury;
- e. Negligent and careless failure to explain the mechanism, mode, and types of adverse events associated with Abilify;
- f. Negligent representations that Abilify was safe or well-tolerated; and
- g. Negligent and careless failure to issue adequate post-sale warnings that Abilify causes an increased risk of compulsive behaviors, including pathological gambling.

198. Despite the fact that Defendants knew or should have known that Abilify caused unreasonable and dangerous side effects, and that consumers such as Plaintiffs would thereby foreseeable suffer harm, Defendants continued to market Abilify while willfully and deliberately failing to exercise due care in the provision of adequate warnings of Abilify's dangerous propensities.

199. As a direct and proximate result of Defendants' negligence, Plaintiffs suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiffs will suffer the losses in the future.

**AS AND FOR A FIFTH CAUSE OF ACTION: NEGLIGENT MISREPRESENTATION**

200. Plaintiffs hereby repeat, reallege, and reiterate each and every allegation in the preceding paragraphs as if fully restated herein.

201. Defendants owed a duty in all of their several undertakings, including in the communication and dissemination of information concerning Abilify, to exercise reasonable care to ensure that they did not create unreasonable risks of personal injury to others.

202. Defendants misrepresented to consumers and physicians, including Plaintiffs and Plaintiffs' physicians and the public in general, that Abilify was safe or well-tolerated when used as instructed, and that Abilify was safe or well-tolerated, when, in fact, Abilify was dangerous to the well-being of patients.

203. At the time Defendants promoted Abilify as safe or well-tolerated, they did not have adequate proof upon which to base such representations, and, in fact, knew or should have known that Abilify was dangerous to the well-being of Plaintiffs and others.

204. Defendants failed to exercise reasonable care and competence in obtaining or communicating information regarding the safe use of Abilify and otherwise failed to exercise reasonable care in transmitting information to Plaintiffs, Plaintiffs' physicians, and the public in general.

205. Defendants made the aforesaid representations in the course of Defendants' business as designers, manufacturers, and distributors of Abilify despite having no reasonable basis for their assertion that these representations were true or without having accurate or sufficient information concerning the aforesaid representations. Defendants were aware that without such information they could not accurately make the aforesaid representations.

206. At the time the aforesaid representations were made, Defendants intended to induce Plaintiffs or Plaintiffs' physicians to rely upon such representations.

207. At the time the aforesaid representations were made by Defendants, and at the time Plaintiffs received Abilify, Plaintiffs or Plaintiffs' physicians, and the public in general, reasonably believed them to be true. In reasonable and justified reliance upon said representations, Plaintiffs used Abilify.

208. As a direct and proximate result of reliance upon Defendants' misrepresentations, Plaintiffs suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiffs will suffer the losses in the future.

**AS AND FOR A SIXTH CAUSE OF ACTION: NEGLIGENCE PER SE – VIOLATIONS  
OF 21 U.S.C. §§ 331, 352 AND 21 C.F.R. §§ 201.56, 201.57, 202.1**

209. Plaintiffs hereby repeat, reallege, and reiterate each and every allegation in the preceding paragraphs as if fully restated herein.

210. At all times herein mentioned, Defendants had an obligation to abide by the law, including the Federal Food, Drug and Cosmetic Act and its applicable regulations, in the manufacture, design, formulation, compounding, testing, production, processing, assembling, inspection, research, promotion, advertising, distribution, marketing, labeling, packaging, preparation for use, consulting, sale, warning, post-sale warning, and other communications of the risks and dangers of Abilify.

211. By reason of their conduct as alleged herein, Defendants violated provisions of statutes and regulations including, but not limited to, the following:

- a. Defendants violated the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 331 and 352, by misbranding Abilify;
- b. Defendants failed to follow the “[g]eneral requirements on content and format of labeling for human prescription drugs” in violation of 21 C.F.R. § 201.56;
- c. Defendants failed to follow the “[s]pecific requirements on content and format of labeling for human prescription drugs” in violation of 21 C.F.R. § 201.57;
- d. Defendants advertised and promoted Abilify in violation of 21 C.F.R. § 202.1; and
- e. Defendants violated 21 C.F.R. § 201.57(e) by failing to timely and adequately change the Abilify label to reflect the evidence of an association between Abilify and the serious compulsive behaviors suffered by Plaintiffs.

212. These statutes and regulations impose a standard of conduct designed to protect consumers of prescription drugs, including Plaintiffs.

213. Defendants’ violation of these statutes and regulations constitutes negligence per se.

214. As a direct and proximate result of Defendants’ statutory and regulatory violations, Plaintiffs, members of the class of persons intended to be protected by the above-mentioned statutes, suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic

losses, and aggravation of previously-existing conditions. The losses are either permanent or ongoing, and Plaintiffs will suffer such losses in the future.

**AS AND FOR A SEVENTH CAUSE OF ACTION: VIOLATION OF CONSUMER  
PROTECTION LAWS**

215. Plaintiffs hereby repeat, reallege, and reiterate each and every allegation in the preceding paragraphs as if fully restated herein.

216. By reason of the conduct as alleged herein, and by inducing Plaintiffs and Plaintiffs' physicians to use Abilify through the use of deception, fraud, false advertising, false pretenses, misrepresentations, unfair or deceptive practices, or a combination of these acts, and the concealment and suppression of material facts including, but not limited to, fraudulent statements, concealments, and misrepresentations identified herein and above, Defendants violated state consumer protection statutes.

217. As a direct and proximate result of Defendants' statutory violations, Plaintiffs were damaged by Abilify, which would not have occurred had Defendants not used deception, fraud, false advertising, false pretenses, misrepresentations, unfair or deceptive practices, or a combination of these acts, and the concealment and suppression of material facts to induce Plaintiffs and Plaintiffs' physicians to use this product.

218. By reason of such violations, Plaintiffs suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously-existing conditions. The losses are either permanent or ongoing, and Plaintiffs will suffer such losses in the future.

**AS AND FOR AN EIGHTH CAUSE OF ACTION: FRAUDULENT CONCEALMENT**

219. Plaintiffs hereby repeat, reallege, and reiterate each and every allegation in the preceding paragraphs as if fully restated herein.

220. At all material relevant times mentioned herein, Defendants had the duty and obligation to disclose to Plaintiffs and Plaintiff's physicians the true facts concerning Abilify; that is, that Abilify is dangerous and defective, and likely to cause serious health consequences to users, such as those alleged herein, without providing a significant benefit.

221. Throughout the relevant time period, Defendants knew that Abilify was defective and unreasonably unsafe for its intended purpose.

222. Defendants fraudulently concealed from or failed to disclose or to warn Plaintiffs, Plaintiffs' physicians, and the medical community that Abilify was defective, unsafe, unfit for the purposes intended, and was not of merchantable quality.

223. Defendants were under a duty to Plaintiffs to disclose and warn of the defective nature of Abilify because:

- a. Defendants were in a superior position to know the true quality, safety and efficacy of Abilify;
- b. Defendants knowingly made false claims about the safety and quality of Abilify in the documents and marketing materials Defendants provided to the FDA, physicians, and the general public; and
- c. Defendants fraudulently and affirmatively concealed the defective nature of Abilify from Plaintiffs.

224. Defendants were under a duty to Plaintiffs to disclose and warn of the defective nature of Abilify because the facts concealed or not disclosed by Defendants to Plaintiffs were

material facts that a reasonable person would have considered to be important in deciding whether or not to purchase or use the product.

225. Defendants intentionally, willfully, and maliciously concealed or failed to disclose the true defective nature of Abilify so that Plaintiffs would request and purchase Abilify, and that their healthcare providers would dispense, prescribe, and recommend Abilify, and Plaintiffs justifiably acted or relied upon, to Plaintiffs' detriment, the concealed or non-disclosed facts as evidenced by his purchase and use of Abilify.

226. At all material relevant times mentioned herein, Plaintiffs and their physicians were unaware of the concealed facts set forth herein. Had they been aware of those facts, they would not have acted as they did; that is, they would not have prescribed and/or taken Abilify, and Plaintiffs would therefore not have been injured.

227. Defendants, by concealment or other action, intentionally prevented Plaintiffs and Plaintiffs' physicians from acquiring material information regarding the lack of safety and effectiveness of Abilify, and are subject to the same liability to Plaintiffs for Plaintiffs' pecuniary losses, as though Defendants had stated the non-existence of such material information regarding Abilify's lack of safety and effectiveness and dangers and defects, and as though Defendants had affirmatively stated the non-existence of such matters that Plaintiffs were thus prevented from discovering the truth. Defendants therefore have liability for fraudulent concealment under all applicable law, including, *inter alia*, Restatement (Second) of Torts § 550 (1977).

228. As a result of Defendants' foregoing acts and omissions, Plaintiffs were and still are caused to suffer and are at a greater increased risk of serious and dangerous side effects including compulsive gambling, and other severe and personal injuries, physical pain and mental anguish, diminished enjoyment of life, any and all life complications.

229. As a direct and proximate result of the foregoing acts and omissions, Plaintiffs have required and will require healthcare and services, and have incurred financial loss, medical, health care, incidental, and related expenses.

230. As a direct and proximate result of reliance upon Defendants' misrepresentations, Plaintiffs suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiffs will suffer the losses in the future.

**AS AND FOR AN NINTH CAUSE OF ACTION: LOSS OF CONSORTIUM**

231. Plaintiffs hereby repeat, reallege, and reiterate each and every allegation in the preceding paragraphs as if fully restated herein.

232. Plaintiffs' spouses have incurred financial loss as a result of Defendants' conduct.

233. As a result of Defendants' conduct, Plaintiffs' spouses were caused to suffer, and will continue to suffer in the future, loss of consortium, loss of society, affection, assistance, and conjugal fellowship, all to the detriment of their martial relationship.

234. Defendants have caused significant harm to Plaintiffs and the Class, including harm to the properties and water supplies of Plaintiffs and the Class and have demonstrated a conscious and outrageous disregard for their safety with implied malice, warranting the imposition of punitive damages.

**AS AND FOR AN TENTH CAUSE OF ACTION: PUNITIVE DAMAGES**

235. Plaintiffs hereby repeat, reallege, and reiterate each and every allegation in the preceding paragraphs as if fully restated herein.



236. Plaintiffs are entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, and malicious acts, omissions, and conduct, as well as Defendants' reckless disregard for Plaintiffs' and the public's safety and welfare. Defendants intentionally and fraudulently misrepresented facts and information to both the medical community and the general public, including Plaintiffs, by making intentionally false and fraudulent misrepresentations about the safety and efficacy of Abilify. Defendants intentionally concealed the true facts and information regarding the serious risks of harm associated with the ingestion of Abilify, and intentionally downplayed the type, nature, and extent of the adverse side effects of ingesting Abilify, despite Defendants' knowledge and awareness of the serious side effects and risks associated with Abilify.

237. Defendants had knowledge of and were in possession of evidence demonstrating that Abilify caused serious side effects including compulsive gambling. Notwithstanding Defendants' knowledge of the serious side effects of Abilify, Defendants continued to market the drug by providing false and misleading information with regard to the product's safety and efficacy to the regulatory agencies, the medical community, and consumers of Abilify.

238. Although Defendants knew or recklessly disregarded the fact that Abilify causes debilitating compulsive behavior side effects including compulsive gambling, Defendants continued to market, promote, and distribute Abilify to consumers, including Plaintiffs, without disclosing these side effects when there were alternative methods for treating Plaintiffs' underlying conditions.

239. Defendants failed to provide warnings that would have dissuaded physicians from prescribing Abilify and consumers from purchasing and ingesting Abilify, thus depriving both

from weighing the true risks against the benefits of prescribing, purchasing, or consuming Abilify.

240. Defendants knew of Abilify's defective nature as set forth herein, but continued to design, manufacture, market, distribute, sell, and promote the drug as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiffs, in a conscious or negligent disregard of the foreseeable harm caused by Abilify.

241. The aforementioned conduct of Defendants was committed with knowing, conscious, reckless, and deliberate disregard of the rights and safety of consumers such as Plaintiffs, thereby entitling Plaintiffs to punitive damages in the amount appropriate to punish Defendants and deter them from similar conduct in the future.

#### **PRAYER FOR RELIEF**

242. WHEREFORE, the Plaintiffs and the Class demand judgment against Defendants, and each of them, jointly and severally, and request the following relief from the Court:

- A. Awarding actual Damages to Plaintiff incidental to the purchase and ingestion of Abilify in an amount to be determined at trial;
- B. Awarding the costs of treatment for Plaintiff's injuries caused by Abilify;
- C. Awarding damages for Plaintiff's neuropsychiatric, mental, physical, and economic pain and suffering;
- D. Awarding damages for Plaintiff's mental and emotional anguish;
- E. Awarding pre-judgment and post-judgment interest to Plaintiff;
- F. Awarding punitive damages;
- G. Awarding the costs and expenses of this litigation to Plaintiff;
- H. Awarding reasonable attorney's fees and costs to Plaintiff as provided by law; and

I. For such further relief as this Court deems necessary, just and proper.

**JURY DEMAND**

Plaintiffs demand a trial by jury of any and all issues in this matter so triable pursuant to Federal Rule of Civil Procedure 38(b).

Dated: August 13, 2018

Respectfully Submitted,

**NAPOLI SHKOLNIK, LLC**

**By:** /s/ R. Joseph Hrubiec  
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